UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,151	01/27/2005	Tomas Carlsson	20166-0007US1	8701

26181 7590 12/09/2009

FISH & RICHARDSON P.C.
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
BADR, HAMID R	

ART UNIT	PAPER NUMBER
1794	

NOTIFICATION DATE	DELIVERY MODE
12/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/523,151	CARLSSON, TOMAS	
	Examiner	Art Unit	
	HAMID R. BADR	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 0209*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11, 42--44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 42--44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' amendment filed 10/30/2009 is acknowledged.

2. Applicants' Application Data Sheet filed 10/30/2009 regarding a change to the title of the invention has been considered. The change to the title has been accepted and entered.

3. Claims 1-11 and 42-44 are being considered on the merits.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Case law holds that applicant's specification must be "commensurately enabling [regarding the scope of the claims]" *Ex Parte Kung*, 17 USPQ2d 1545, 1547 (Bd. Pat. App. Inter. 1990). Otherwise **undue experimentation** would be involved in determining how to practice and use applicant's invention. The test for undue experimentation as to whether or not all compounds within the scope of claims 4 can be used as claimed and whether claim 4 meets the test is stated in *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App.

Inter. 1986) and *In re Wands*, 8 USPQ2d 1400, 1404 (Fed.Cir. 1988). Upon applying this test to claim 4, it is believed that undue experimentation **would** be required because: Using nitrogen gas to adjust pH of a solution is not technically possible. There are no working examples as how to adjust the pH of a protein hydrolysate using nitrogen gas.

5. Claims 1-11 and 42-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 1, step d, the phrase "calcium base" has no support in the specification. Applicants refer to paragraph [00278] on page 30 of application for support. However, paragraph [00278] does not support the phrase.

6. Claim 6 has been amended to include "sodium chloride". The specification has no support for this phrase. Applicants refer to page 20, line 1 for supporting this phrase, however, there is no support for this phrase on page 20, line 1 of the instant specification.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 1 is indefinite for " step d. pH of the water is adjusted by adding calcium base". It is not clear what is meant by "calcium base". It is unclear what the applicant regards as the invention.

10. Claim 4 is indefinite for "pH adjuster in step f is nitrogen gas, calcium base". It is unclear how nitrogen gas is used to adjust pH of the protein hydrolysate or what is meant by "calcium base".

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-10 rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 5,053,234; here in after R1).

13. R1 discloses a method for producing protein hydrolysate. The method comprises using abattoir remains, fillet frames, trash fish, animal by products, usable entrails, and the like as raw materials (Col. 5, lines 54-57), grinding the raw materials using a grinder (Col. 6, lines 35-40), heating the ground raw material (Col. 6, lines 59-63), hydrolyzing the proteins in the ground material using either endogenous or extraneous proteolytic enzymes. (Col. 7, lines 3-20), adding water to the ground material (Col. 7, lines 34-40),

adjusting the pH within the range 6.0-6.5 (Col. 7, lines 49-50), controlling the hydrolysis temperature at 60-65C, (Col. 7, lines 54-65), heat deactivating the enzymes at 79-93C, causing the rendering of fatty materials in addition to deactivation of enzymes (Col. 10, lines 29-40), screening the digested material to remove large particles (Col. 10, lines 44-52), screening of undigested material and re-circulating the undigested material to the digestion stage (Col. Lines 42-45), separating the oil by centrifugation of the mixture (Col. 15, lines 1-5, and 24-25), and concentrating the hydrolyzed protein (Col. 12, lines 14-20). The produce protein hydrolysate can be used as animal feed. (Col. 17, lines 28-34).

14. Given that the heating stage involves the denaturation and coagulation of proteins, it is obvious that coagulated material can be separated using proper means known in the art.

15. Given that the water content of the ground raw material will affect the handling, and flow properties as well as the dispersion of enzymes in the ground material, it would be obvious to adjust the water content to levels as presently claimed.

16. It is also obvious to carry out the process batch wise as presently claimed. Using acids and bases to adjust the pH is also within the skill of the artisan.

17. Given that any rendered fatty material can be separate from the digested material as disclosed by R1, the fat content of the hydrolysate can be adjusted to predetermined levels including the presently claimed fat content.

18. Given that the protein hydrolysate can be prepared with various standards of quality, production of pharmaceutical grade, food grade, biotechnological grade and

feed grade protein hydrolysate is also obvious to those of skill in the art. Various grades of protein hdyrolysates are also known in the art.

19. Since all aspects of the production of protein hydrolysates are disclosed by R1, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to follow and modify the teachings of R1. One would do so to prepare protein hydrolysates having various quality standards for various purposes. Absent any evidence to contrary and based on the teachings of the cited reference, there would be a reasonable expectation of success in preparing protein hydrolysates.

20. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 5,053,234; here in after R1), further in view of JP-2-97409 (hereinafter R2).

21. The disclosure by R1 is hereby incorporated by reference as outlined above.

22. While R1 is silent regarding the production of hydroxyapatite, when the raw material contains bones, a large quantity of the undigested material remaining after the hydrolysis will comprise bones. The bones remaining after the digestion stage, can be used for the production of hydroxyapatite.

23. R2 discloses a method for producing natural hydroxyapatite out of fish bones. (Abstract).

24. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to follow the teachings of R1 to produce protein hydrolysates and convert the remaining bones after the hydrolysis; following the method

as disclosed by R2. One would do so to prepare a value added product form waste material. Absent any evidence to contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success in converting bones to hydroxyapatite.

Response to Arguments

Applicants arguments have been reviewed carefully. These arguments are not deemed persuasive for the following reasons:

1. Applicants argue that the proteins as disclosed by Anderson (R1) have a target value of the number-average molecular weight in the range of about 15000 to about 30000 daltons and that these are different from the presently claimed peptides/amino acids.

a. This range is recited by Anderson, however, Anderson states that other values can be selected and reliably achieved, depending on the intended use of the product. It should be realized that the products can be varied by changing the parameters as disclosed by Anderson, however, those modifications will be obvious to those of skill in the art regarding the disclosure by Anderson.

2. Applicants argue that the products of the presently claimed invention are not non-denatured proteins.

a. Separation of peptides/amino acids from proteins (whether denatured or undenatured) would be obvious and within the skill of the art. On the other hand, applicants are using a temperature range (before heating the mixture) at which the

proteins will remain undenatured. However, at the heating stage, according to Anderson and according to stage g of claim 1, any remaining undigested protein will be denatured. It is also noted that denaturation, as applied to proteins, is not applicable to short peptides and amino acids, therefore, when such compounds are produced, according to the process as disclosed by Anderson, they will not be affected by heat regarding the denaturation process.

3. Applicants argue that the Anderson method produces a mixture having "about 20-35% oil/fat derived from animal parts.

a. The product as disclosed by Anderson can contain oil/fat derived from animal parts. However, Anderson discloses that the amount of oil removed from the suspension via passage through the centrifuge is governed by several variable. It is thus within the skill of the art, to change those variables to produce a product with any desired level of oil/fat including the levels as presently claimed.

4. Applicants argue that in the presently claimed invention the proteins are coagulated and removed by applying a low pH to the reaction feed, and that Anderson proteins remain in the final product.

a. The undigested protein can be separated either by heat coagulation or pH adjustment. To separate the undigested protein, by any means known in the art, would be within the skill in the art. Furthermore, claim 1, step j, requires "coagulating the proteins". This requirement is also satisfied by Anderson.

5. Applicants argue that JP-297409 does not provide the disclosure s that are missing for Anderson.

a. JP-297409 is used as a secondary reference to disclose the preparation of hydroxyapatite from fish bone, which has been presently claimed.

It should be realized that the rejection is an obviousness type rejection, in which modifications of Anderson's teachings can be made by those of skill in the art. In other words, in light of the teachings by Anderson, the presently claimed invention is obvious to those of skill in the art. The hydrolysis of animal protein using endogenous or exogenous enzymes is fully disclosed by Anderson. The degree of hydrolysis of the proteins, as well as separation of short peptides/amino acids from undigested proteins would be obvious versions of what is disclosed by Anderson.

Conclusion

25. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr
Examiner
Art Unit 1794

/Keith D. Hendricks/

Supervisory Patent Examiner, Art Unit 1794